IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA,

Plaintiff,

ex rel.

[UNDER SEAL],

v.

[UNDER SEAL],

Defendants.

Case No. CIV-15-114-M

PLAINTIFF-RELATOR'S COMPLAINT

[redacted]

CONFIDENTIAL
ATTORNEY WORK PRODUCT
[redacted]

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA, and the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, WISCONSIN, the DISTRICT OF COLUMBIA, and the CITY OF CHICAGO,

Plaintiffs,

Ex rel.,

JAMIE SIEGEL, M.D.,

Plaintiff-Relator,

v.

NOVO NORDISK, INC.,

Defendant.

FILED

FEB 2 2015

CARMELITA REEDER SHINN, CLERK
U.S. DIST. COURT, WESTERN DIST. OKLA
BY _____, DEPUTY

COMPLAINT

[redacted]

JURY TRIAL DEMANDED

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I. INTRODUCTION

1. Hemophilia is a rare, but life-threatening, genetic bleeding disorder, in which the blood does not clot normally. Persons afflicted with this disease bleed for longer than others after an injury. They also bleed internally, especially in their knees, ankles and elbows, where external pressure cannot be applied, causing permanent damage to organs and tissues, resulting in deformed joints, limited mobility and chronic pain. For individuals with hemophilia, unchecked bleeds can lead to serious health problems, such as immobility, neurologic damage, and death. Clotting "factors" are proteins in the blood required for normal blood clotting: they work with platelets that form in the bone marrow and proteins in body tissues to form clots that stop bleeds. Hemophilia, which is life-long and for which there is no cure, affects approximately 20,000 people in the U.S., mostly men.

2. In the 1960's, doctors learned to isolate the missing factors from the plasma of normal individuals, and infuse them into the bloodstream of hemophiliacs to help them clot normally. In the late 1980's, Novo Nordisk ("Novo") and other pharmaceutical companies developed methods to manufacture factors using recombinant techniques, so as to prevent transmission of blood-borne diseases like HIV and hepatitis C from human donors.

3. Of those patients born with hemophilia (deficient or absent Factor VIII or Factor IX), approximately 15-20% will develop an antibody, called an inhibitor, to their deficient or missing protein. This inhibitor will inactivate the corresponding infused clotting factor and render it ineffective, so that the patient once again cannot stop bleeding. For this reason, patients with hemophilia who have an inhibitor often need what is called a bypassing agent, such as Defendant Novo Nordisk's NovoSeven and NovoSeven RT (together, "NovoSeven®"), at issue in this case, to stop painful bleeds.

4. NovoSeven® is approved by the FDA for the treatment of patients with hemophilia A or B with inhibitors. The approval is for use to treat bleeding episodes or to prevent excessive bleeding during surgical interventions or invasive procedures. It is not indicated for use on a routine basis (i.e. several times per week or daily) to *prevent* spontaneous bleeds from occurring in the first place – a treatment strategy referred to as "prophylaxis."

5. NovoSeven®'s package insert also directs injections at a dosage of 90 mcg/kg of NovoSeven® every 2 hours until the bleed has stopped.

6. Defendant Novo Nordisk ("Novo") sought to prey on a vulnerable population, patients with hemophilia, by marketing its hemophilia treatments NovoSeven® and NovoSeven RT® off-label to be used at excessive doses and for prophylaxis, even though NovoSeven® has never been approved for these uses by the Food and Drug Administration ("FDA"). NovoSeven® did not secure these indications because it could not demonstrate that NovoSeven® was either safe or effective for these uses. Specifically, Novo never conducted the planned phase 3 study of NovoSeven® for prophylaxis. The data Novo submitted to the FDA for the prophylaxis indication was based on a study, led by Dr. Barbara Konkle (hereafter "Konkle Study"),[1] of 22 patients evaluated for a change in bleeding episodes from baseline, during, and for three months after prophylaxis treatment. These results did not provide sufficient evidence for the FDA to expand NovoSeven's indication.

7. In addition, Novo never demonstrated that a higher dose of NovoSeven® –180 mcg/kg to 300 mcg/kg was superior to the approved dose of 90 mcg/kg for acute bleeds.

[1] B.A. Konkle,, L.S. Ebbesen, E. Eehardtson, R.P. Bianco, T. Lissitchkov, L. Rusen and M. A. Serban, *Randomized, prospective clinical trial of recombinant factor VIIa for secondary prophylaxis in hemophilia patients with inhibitors*, Journal of Thrombosis and Hemostasis, 5:1904-1913 (2007).

8. Rather than undertake a controlled clinical study to evaluate high dose therapy or prove NovoSeven®'s safety and efficacy for prophylaxis, Novo chose to bypass the FDA approval process and promote both high dose and prophylaxis with flimsy anecdotal data through a number of tactics, violating the Food Drug and Cosmetics Act, the Anti-Kickback Statute, the federal False Claims Act and similar state and municipal false claims act statutes, including:

- Paying kickbacks to physicians to prescribe NovoSeven® for on-label and off-label uses via the Hemostasis and Thrombosis Research Society Registry ("HTRS Registry"), which was initiated by Novo to fulfill FDA-required post-marketing data collection of NovoSeven®;
- Paying well known hemophilia physicians to sign manuscripts, actually written by Novo employees and/or influenced by Novo editors, which were submitted to leading hemophilia medical journals, touting "data" based on opinion, poorly controlled studies, registries (including the HTRS Registry), and a compilation of case reports supporting the use of NovoSeven® for off-label purposes, specifically prophylaxis and at higher doses;
- Paying high-profile hemophilia doctors, designated as Key Opinion Leaders ("KOLs") to use their influence – via journal articles, speaking events, and participation in educational events – to persuade health care providers, patients, hemophilia advocacy groups, hemophilia professional societies and home health companies specializing in hemophilia care, to use NovoSeven® off-label for prophylaxis and at higher doses;
- Sponsoring and hosting "all-expenses paid" events for individuals with hemophilia and inhibitors, such as camps for children and summits or "weekend retreats" for adults and adolescents at which Novo promoted the use of NovoSeven® for off-label purposes, specifically prophylaxis and at higher doses;
- Paying well known hemophilia physicians to "mingle" and speak at these patient events; and
- Paying high-profile adult patients who have hemophilia with inhibitors who use NovoSeven® for prophylaxis to promote such use to other patients, including through patient literature disseminated by Novo and/or at hemophilia camps for children or weekend retreats for adult patients, which are supported by or paid for entirely by Novo.

9. Factors are quite expensive – NovoSeven® especially so – and much of the cost is borne by Federal and state governments through Medicare (Part B) and Medicaid. For example,

an HHS OIG report issued in October 2011[2] found that Medicare paid $46,349,026 to the Indiana Hemophilia and Thrombosis Center for NovoSeven®, reportedly used as indicated by a total of six patients over two years. That comes to approximately $4 million per patient per year. According to a 2013 report by the Medicaid Health Plans of America[3], approximately a third of the people with hemophilia are covered through state Medicaid programs. Likewise, a 2011 study showed that over 40% of the 3380 young men and boys with severe hemophilia studied were covered by Medicare and Medicaid.[4] The same study shows that over 51% of these individuals were covered by "commercial insurance."

10. The high cost of hemophilia treatments has a significant impact on government healthcare programs. Both in Medicare and Medicaid, health care providers, such as the Hemophilia Treatment Centers ("HTCs"), doctors or home care companies, buy clotting factors from the manufacturers wholesale, but charge the patients' insurers, including Medicare and Medicaid, retail. That is, there is a markup which allows providers to profit from each unit they prescribe. Moreover, for Medicare this markup is particularly large because of another federal program called the 340B Discount Drug Pricing Program ("340B").[5] Under 340B, manufacturers are required to sell factors to providers at a significant discount from their usual

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[2] *Review of Medicare Payments for NovoSeven Coagulation Factor VIIa to Indiana Hemophilia and Thrombosis Center, Inc. from January 1, 2008 through December 31, 2009*, Department of Health and Human Services' Office of Inspector General, October 2011 (A-05-11-00027).

[3] *Addressing the Needs of Members with Hemophilia in Medicaid Managed Care: Issues and Implications for Health Plans*, Medicaid Health Plans of America Clinical Brief, July 22, 2013.

[4] Judith R. Baker et al., *Insurance, Home Therapy, and Prophylaxis in U.S. Youth with Severe Hemophilia*, Am. J. Prev. Med. 2001; 41 (6S4), p. S340 at Table 1. The study also stated, "Participants insured by Medicare were significantly more likely to use prophylaxis than were those insured by commercial plans." *Id.* at pg. S340 (in the text).

[5] Section 340B of the Public Health Service Act, 42 U.S.C. § 256b *et seq.*

wholesale price. Medicare pays providers, however, the same retail price whether the providers have used 340B or not, generating a significantly increased profit.

11. Because of this, doctors at HTCs have an incentive to prescribe NovoSeven® and other hemophilia factors to patients insured through Medicare or private insurance at higher and more frequent doses than they would without the 340B discount. In such instances, both the drug manufacturer and the HTC profit, but Medicare (or private insurance) winds up paying for treatments that would otherwise not have been prescribed. The amount of revenue generated by 340B participation can be significant. For example, one HTC in Indiana headed by Novo KOL Dr. Amy Shapiro, examined in the 2011 OIG review reported that 340B revenue accounted for about 97% of its total budget and was used to support all of its program operations. While the structure of the 340B program contemplates that some covered entities may benefit from the spread between discounted drug prices and reimbursement drug prices, 340B covered entities are not exempt from either the Stark Act or the Anti-Kickback Act.[6] Providers can also use 340B to buy factors for their Medicaid patients. However, if they do, the State Medicaid programs cannot obtain rebates from manufacturers that they would otherwise be entitled to. (This would amount to a "double discount" from the manufacturer, which is specifically prohibited by 340B.) So providers generally do not use 340B for patients with hemophilia on Medicaid.

12. Medical supply companies, called home health care companies ("HHCCs"), which provide factor to patients with hemophilia, also benefit from the increased use of NovoSeven®: they too earn profits based upon their volume of sales of factor. While HHCCs do not qualify for 340B discounts their arrangements with Novo for purchase of NovoSeven® do

[6] OIG Advisory Request No. 98-15, https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_15.htm

generate significant profits like those of the HTCs. A 2003 GAO Report,[7] estimates that these companies receive discounts of 22 to 40 percent below average wholesale price ("AWP"). For this reason, the increased use (or overuse) of factor is so lucrative for HHCCs that some companies hire patients with hemophilia to recruit other patients with hemophilia to use factor for prophylaxis or at higher doses. Overuse of factor affects all health care plans, including those funded by the government or by employers/employees. Finding hemophilia patients to promote prophylaxis to other patients is not difficult in a small community of men closely tied together by support groups based on their unusual, severe common problem.

13. Relator Jamie Ellen Siegel MD, a physician who began her training as a fellow in hemophilia at Thomas Jefferson University, Cardeza Foundation Hemophilia Center in 1987, specialized in coagulation and thrombosis: she has remained involved in the community since that time. Her last clinical position was as Clinical Associate Professor of Medicine, Cardeza Foundation for Hematologic Research and Division of Hematology, Thomas Jefferson University. She was also the Director of the Hemophilia and Thrombosis Center and the Medical Director of the Cardeza Foundation Special Hemostasis Laboratory. She served in these roles from November 2001 until December 2007. While at Thomas Jefferson University, Dr. Siegel was asked to assume the position of Chair of the NovoSeven® Ad Hoc Committee to look into use of this expensive medication. She has first-hand knowledge of Novo's deliberate strategy to promote off-label use of NovoSeven® for prophylaxis, and off-label dosing regimens, which continues to this day, through documents evidencing the fraudulent scheme as well as

[7] U.S. Gov't Accountability Office, GAO-03-184, *Medicare Payment for Blood Clotting Factor Exceeds Providers' Acquisition Cost*, GAO Report to the ranking Minority Member, Subcommittee on Health, Committee on Ways and Means, House of Representatives, January 2003 (summary p. 1).

inside knowledge of the pharmaceutical industry and, particularly, Novo where she worked from 2008-2009.

14. Though Dr. Siegel was hired by Novo as its Director of Hematology in Clinical Development in January 2008, she quickly learned that Novo had *not* hired her to design new clinical trials for NovoSeven®, as she was told in interviews, but to exploit her connections within the hemophilia community to promote NovoSeven® for the off-label indications, prophylaxis and high-dose regimens. Indeed, within the first few weeks and months of her tenure at Novo, she primarily attended marketing meetings with representatives from the marketing, sales and clinical divisions of the company to discuss the potential off-label uses for NovoSeven®. At this time, Novo had tried to expand its NovoSeven® market share by promoting the drug for trauma and neurosurgery applications – to help non-hemophiliacs clot faster – but the strategy yielded relatively few new sales opportunities: the one time acute nature of neurosurgeries and trauma injuries resulted in the use of one or two doses per event. Novo had failed to get an indication for these uses.

15. Indeed, Novo's unlawful marketing of NovoSeven® for trauma surgeries (for non-hemophilia patients) eventually led to a False Claims Act case, which was settled with the Government in 2011. When Dr. Siegel was hired, Novo was searching for another way to expand its sales for NovoSeven® beyond the small number of patients who have hemophilia with inhibitors *and* its narrow indication, limited to "on demand" treatment of acute bleeds.

16. To assist the off-label marketing of NovoSeven®, Novo sought Dr. Siegel's help, *inter alia*, to work with several Novo Key Opinion Leaders ("KOL's") to expand the off-label uses of NovoSeven®; to review and edit journal articles for physicians Novo selected to publish articles supporting off-label use; and to participate in marketing meetings to brainstorm ideas for

promoting NovoSeven® off-label. After one such brainstorming meeting in Switzerland in early 2008, she was contacted directly by high level physicians from Novo's Zurich office who pressured her to use her relationships in the U.S. to get physicians to agree to sign journal articles written by Novo in support of off-label prophylaxis use of NovoSeven®. Dr. Siegel refused to do so.

17. In 2008, Dr. Siegel designed a study to determine whether increasing single doses of NovoSeven® would result in safe and more effective control of acute joint bleeds in hemophilia patients with an inhibitor. This study would have evaluated the effectiveness of increasing doses of NovoSeven® for control of joint bleeding. It would have been able to differentiate dose requirements based on the specific joint and whether or not the joint was already damaged ("arthropathy") and/or was considered to be a "target" joint (a joint likely to bleed in a particular patient). The study would have provided an individualized assessment for each patient enrolled. The company aborted the study when it learned that the study was designed to actually determine the correct dosing through a step-wise dosing design rather than to demonstrate the need for high dose treatment for all patients. Believing that the outcome might actually reduce the dose currently being prescribed for some or all patients, Novo managers instructed Dr. Siegel and others not to proceed: Novo had no interest in learning to use NovoSeven® more effectively, if that might lower revenue for the drug. Meanwhile, Novo continued to market the drug – through ghost written studies, case reports, and other tactics enumerated above – for high doses even though no well controlled studies established the efficacy or safety of such doses.

18. Likewise, there are significant potential harms associated with the use of NovoSeven® for prophylaxis such as thromboembolism, and infections caused by the use of a

central line to administer NovoSeven® on a daily or routine basis. NovoSeven® poses significant risks for hemophilia patients when used off-label for prophylaxis, or at higher doses. Unlike Factors VIII and IX, which are used to replace identical factors missing from the bloodstream of hemophilia patients, NovoSeven® promotes clotting in a non-physiological way, that is, not the way a healthy person clots. Therefore, the FDA has placed a black box warning, its most serious, on the label for Novo7; Factors VIII and IX, by contrast, carry no such warning. In the black box, the FDA warns of increased risks of thrombosis, that is, clots where they should not occur, when NovoSeven® is used off-label. At the bottom of the black box, the FDA emphasizes: "Safety and efficacy of NovoSeven RT has not been established outside the approved indications." (Emphasis in the original.) In Section 5.3 of the label, FDA advises that "Precautions should be exercised when NovoSeven RT is used for prolonged dosing", with a reference to Section 2.2, which states that: "The biological and clinical effects of prolonged elevated levels of Factor VIIa have not been studied; therefore, the duration of post-hemostatic dosing should be minimized."

19. Because of Novo's off-label marketing and kickbacks, federal, state and local government health care programs, as well as private insurers operating in the State of California, have been fraudulently induced to pay for off-label NovoSeven® prescriptions that never have been submitted for reimbursement but for Novo's activities. In addition to the federal healthcare dollars expended through Medicare and Medicaid, state governments spend money through Medicaid, as well as through their state workers' insurance plans. Had federal, state and city programs, including Medicare and Medicaid, as well as private insurers including those in the State of California, known that such prescriptions were induced by illicit incentives or illegal off-

label marketing to physicians and patients, they would not have reimbursed for claims for NovoSeven®.

20. This is especially significant because of the high cost of NovoSeven®, the most expensive hemophilia factor treatment on the market. For example, when NovoSeven® is used for prophylaxis (meaning that it is taken intravenously by the patient every day or multiple times per week) it costs more than $1 million per year/per adult patient. Use of NovoSeven® off-label in high dose regimens also significantly increases the cost of treatment.

21. Novo's global sales of NovoSeven® have steadily climbed, reaching over a billion dollars in 2007. Curiously, Novo attributes the growth of NovoSeven®, in one of its annual reports, to rising prescriptions in the U.S. and Canada even though there has been no change in the market of potential users (i.e. patients with hemophilia and inhibitors) or the drug's limited indication, which has remained substantially unchanged since its initial approval.

22. As noted above, this is not the first time that Novo has been called to account for off-label marketing of NovoSeven®. In June 2011, the Department of Justice ("DOJ") reached a settlement with Novo wherein Novo agreed to pay $25 million to resolve allegations of off-label promotion. The DOJ's press release announcing the settlement stated that Novo "promoted NovoSeven to health care professionals for off-label uses, including as a coagulatory agent for trauma patients, general surgery, cardiac surgery, liver surgery, liver transplants and intra-cerebral hemorrhage. As a result of this unlawful promotion, Novo Nordisk caused false claims to be submitted to government health care programs that were not reimbursable by those programs."

23. As part of its settlement with the Government, Novo entered into a multi-year Corporate Integrity Agreement ("CIA"), ending in 2016, wherein Novo agreed to take numerous

remedial steps to ensure compliance with FDA promotional rules and regulations, among other things. The unlawful conduct alleged herein is on-going and violates Novo's CIA with the Government.

24. Plaintiff-Relator Siegel now brings this qui tam Complaint against Novo on behalf of the United States of America and on behalf of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, Wisconsin, the District of Columbia (the "States"), and the City of Chicago, pursuant to the qui tam provisions of the Federal False Claims Act and similar state and law and municipal provisions, and the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7.

II. PARTIES

25. Plaintiff-Relator Jamie E. Siegel is a citizen of Maryland. She is a graduate of the Medical College of Pennsylvania B.A.-M.D. program, and is licensed to practice medicine in Pennsylvania. She is board-certified in Internal Medicine, Medical Oncology, and Medical Hematology, and is a contributing author of nineteen peer-reviewed published papers, as well as twenty-one published abstracts and seven book chapters. From 2001 to 2008, Siegel was a Clinical Associate Professor of Medicine and a Director of the Hemophilia and Thrombosis Center at Thomas Jefferson University; in 2005, she was the Chair of the NovoSeven Ad Hoc Committee at Thomas Jefferson University Hospital. She also was responsible for oversight of the 340B program at her hemophilia center and was aware of the potential for abuse. She has participated as a researcher in a clinical trial sponsored by Novo Nordisk to evaluate NovoSeven

for reducing bleeding during surgery. From 2008 to 2009, Siegel was a Director of Hematology in Clinical Development, Medical & Regulatory Affairs at Novo Nordisk. Siegel's professional experience in the field of hematology also includes service as a Global Clinical Leader in Hematology in the Global Clinical Development department of Bayer HealthCare Pharmaceuticals Inc., as a Director in the Acquired Bleeding department of CSL Behring, and as Chief of the Thrombosis and Hemostasis Branch for the Division of Blood Diseases and Resources at the National Heart Lung and Blood Institute.

26. Defendant Novo Nordisk, Inc. ("Novo" or the "Company") is a global healthcare company founded 90 years ago in Denmark. Novo specializes in diabetes care, hemophilia care, growth hormone therapy, and hormone replacement therapy. The Company is headquartered in Denmark and employs approximately 36,300 employees in 75 countries, marketing its products in more than 180 countries.

27. Novo's United States operations are incorporated in the state of Delaware under the name Novo Nordisk, Inc. Novo's registered agent is The Corporation Trust Company, located at 1209 Orange Street, Wilmington, Delaware 19801.

28. Novo's United States operations are headquartered in New Jersey at 800 Scudders Mill Road, Plainsboro, New Jersey 08536. The Company has United States production and R&D facilities located in Clayton, North Carolina and Seattle, Washington, respectively. Moreover, according to the Company's website, Novo has sales representatives "in communities in nearly every region of the country."[8]

[8] http://www.novonordisk-us.com/documents/content_pages/branding_page/1_3_Locations.asp

III. JURISDICTION AND VENUE

29. Relator brings this action on behalf of herself and the United States for violations of the False Claims Act, 31 U.S.C. §§ 3729-3733 and on behalf of the States and the City of Chicago for violations of the State False Claims Acts. Relator also brings this action pursuant to Cal. Ins. Code § 1871.7, the California Insurance Frauds Prevention Act. This Court has federal subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732 and supplemental jurisdiction over the counts relating to the State and municipal false claims statutes and the California Insurance Frauds Prevention Act pursuant to 28 U.S.C. § 1367 and 31 U.S.C. 3732.

30. This Court has personal jurisdiction over Novo Nordisk, Inc., pursuant to 31 U.S.C. § 3732(a) because Defendant can be found in and transacts business in this District. In addition, the acts prohibited by 31 U.S.C. § 3729 occurred in this District. 31 U.S.C. § 3732(a).

31. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Novo Nordisk, Inc., transacts business in this District and numerous acts proscribed by 31 U.S.C. § 3729 occurred in this District.

32. Relator's claims and this Complaint are not based upon prior public disclosures of allegations or transactions in a Federal criminal, civil, or administrative hearing in which the Government is already a party, or in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation, or from the news media, as enumerated in 31 U.S.C. § 3730(e)(4)(A).[9]

[9] To the extent that conduct alleged in this Complaint occurred prior to March 23, 2010, the prior versions of the False Claims Act are applicable (*i.e.*, 31 U.S.C. § 3730(e), as amended, October 27, 1986, and May 20, 2009).

33. To the extent that there has been a public disclosure unknown to the Relator, the Relator is the "original source" under 31 U.S.C. § 3730(e)(4)(B).[10] The Relator has independent material knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing this *qui tam* action based on that information. *Id.*

IV. STATUTORY AND REGULATORY PROVISIONS APPLICABLE TO DEFENDANT NOVO'S FALSE CLAIMS VIOLATIONS

A. GOVERNMENT HEALTH PROGRAMS

34. The federal and state governments, through their Medicare and Medicaid programs, are among the principal purchasers of Novo's pharmaceutical products. Medicare is a federal government health program that primarily benefits the elderly and the disabled. It was created by Congress in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS").

35. Part B medical insurance pays for some services and products that are not covered by Part A, usually on an outpatient basis, such as chemotherapy, renal dialysis, outpatient hospital procedures and durable medical equipment. Hemophilia patients on Medicare receiving infusions of factor, including NovoSeven®, are covered by Part B.

36. All Medicare providers certify, *inter alia*, that "payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of

[10] *Id.*

participation in Medicare." CMS Form 855I, Medicare Enrollment Application Physicians And Non-Physician Practitioners (dated 7/11), at 25.[11]

37. Congress created Medicaid at the same time it created Medicare in 1965 by adding Title XIX to the Social Security Act. Medicaid is a public assistance program that provides payment of medical expenses primarily for low-income patients. Funding for Medicaid is shared between the federal and the state governments. The federal government also separately matches certain state expenses incurred in administering the Medicaid program. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, except that Medicaid usually provides more expansive coverage than does Medicare. In particular, Medicaid has broad coverage for prescription drugs. Nearly every state has opted to include basic prescription drug coverage in its Medicaid plan. According to CMS, "[w]hen services are furnished through institutions that must be certified for Medicare, the institutional standards must be met for Medicaid as well. In general, the only types of institutions participating solely in Medicaid are (unskilled) Nursing Facilities, Psychiatric Residential Treatment Facilities, and Intermediate Care Facilities for the Mentally Retarded."[12]

38. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for more than 8 million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including Blue Cross and Blue Shield plans, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the U.S. Office of Personnel Management.

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[11] Available at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf..

[12] *See* http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/index.html?redirect=/certificationandcompliance/02_ascs.asp.

B. THE FALSE CLAIMS ACT

39. The Federal False Claims Act provides that any person who (1) knowingly presents or causes another to present a false or fraudulent claim for payment or approval, or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim is liable for a civil penalty of between $5,500 and $11,000 for each such claim, plus three times the amount of the damages sustained by the government. 31 U.S.C. § 3729(a)(1)(A) & (a)(1)(B), 28 C.F.R. § 85.3. Twenty-two states and the District of Columbia have also enacted False Claims Act statutes that apply to Medicaid fraud.

40. Knowingly paying kickbacks or undisclosed price discounts to physicians to induce them to prescribe a prescription drug reimbursed by a federal government health program, or causing another to do so, while certifying compliance with Medicare, the Medicare Fraud & Abuse/Anti-Kickback Statute, the Medicaid Rebate Statute, or the Food, Drug and Cosmetics Act (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates state and federal False Claims Acts.

C. FDCA AND FDA REGULATIONS

1. Drug Labeling and Advertising That Is False, Misleading Or Lacks Fair Balance Causes Drugs To Be "Misbranded" In Violation of the FDCA and FDA Regulations

41. Pursuant to the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, the Food and Drug Administration ("FDA") strictly regulates the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies to market and sell FDA-approved prescription drugs and biologics.

42. FDA interprets "labeling" in its regulations broadly to include items that are 1) descriptive of a drug; 2) disseminated by the manufacturer or its agents; and 3) intended for use by medical personnel. 21 C.F.R. § 202.1(l)(2). The FDCA defines both misleading statements and the failure to reveal material facts in a label or product labeling as "misbranding." 21 U.S.C. § 321(n). Labeling includes, *inter alia*, brochures, booklets, detailing pieces, literature, reprints, sound recordings, and audio-visual material. 21 C.F.R. § 202.1(l)(2).

43. The FDA regulations deem "advertising" to include media-based activities that appear in magazines, newspapers, professional journals and on television, radio, and telephone communications systems. 21 C.F.R. § 202.1(l)(1).

44. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading "misbrand" a drug in violation of the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 321(n), 331, 352, 21 C.F.R. § 202.1(e)(6), (e)(7), 21 C.F.R. § 1.21.

45. Such violations may exist where promotional and marketing materials and presentations for an FDA approved drug, *inter alia*:

a. Recommend or suggest that the drug be used for conditions not in the labeling;

b. Represent or suggest that a drug is useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience;

c. Use data favorable to a drug derived from patients treated with dosages different from those recommended in approved labeling;

d. Represent or suggest that drug dosages properly recommended for use in the treatment of certain classes of patients or disease conditions are safe and effective

for the treatment of other classes of patients or disease conditions when such is not the case;

e. Contain favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; or

f. Suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations.

See 21 C.F.R. § 202.1 (e)(4)(5)(6), (7).

46. Oral statements and materials presented at industry-supported activities, including lectures and teleconferences, provide evidence of a product's intended use. If these statements or materials promote a use inconsistent with the product's FDA-approved labeling, it is misbranded as it fails to provide adequate directions for all intended uses. 21 C.F.R. § 99.405.

2. Off-Label Marketing Violates the FDCA and FDA Regulations

47. The FDA regulates drugs based on the "intended uses" for such products. Before marketing and selling a prescription drug, a manufacturer must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 355(a).

48. The FDA reviews pharmaceutical manufacturers' applications for new drugs to determine whether the drugs' intended uses are safe and effective. 21 U.S.C. § 355. "Off-label" refers to-the marketing of an FDA-approved drug for uses that have not undergone FDA scrutiny and approval, *i.e.*, for purposes not approved by the FDA.

49. Once a drug is approved for a particular use, doctors are free to prescribe the drug for "non-indicated" or off label purposes. While doctors may request information from drug manufacturers about off-label uses, with very few exceptions the FDA prohibits drug

manufacturers from marketing or promoting drugs for uses – also known as "indications" – not approved by the FDA.

50. Sales and marketing presentations, promotions, or marketing to physicians for uses other than that approved by the FDA is considered off-label marketing proscribed by the FDA with the exception of purely scientific medical information provided by qualified medical professionals. 21 U.S.C. §§ 331(a)-(b), 352(a), (f).

51. Strong policy reasons exist for such strict regulation of off-label marketing. Off-label promotion bypasses the FDA's strict review and approval process. Off-label promotion removes the incentive to obtain definitive clinical study data showing the efficacy and safety of a product and, accordingly, the medical necessity for its use.

52. Any failure to fairly and accurately represent the approved uses, safety and other required information about a prescription drug is considered misbranding and is, as a matter of law, a false and fraudulent statement. 21 U.S.C. §§ 331(a)-(b), 352(a), (f), (n).

D. THE MEDICARE FRAUD & ABUSE/ANTI-KICKBACK STATUTE

53. The Medicare-Medicaid Anti-Fraud and Abuse Amendments, known as the Medicare Anti-Kickback Statute (the "Anti-Kickback Statute"), 42 U.S.C. § 1320a-7b(b) , which also applies to state Medicaid programs, makes it illegal for an individual knowingly and willfully to offer or pay remuneration in cash or in kind to induce a physician to order a good or service that is reimbursed by a federal healthcare program. *See* 42 U.S.C. § 1320a-7b(b)(2). In accordance with the Anti-Kickback Statute, Medicare regulations also prohibit providers from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals paid as a result of the volume or value of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f). "Remuneration" is broadly defined to include

anything of value (including any kickback, bribe, or rebate) paid directly or indirectly, overtly or covertly, in return for purchasing, ordering, or recommending the purchase or order of any item that is reimbursable. *Id.*

54. The Balanced Budget Act of 1997 amended the Medicare Anti-Kickback Statute to include administrative civil penalties of up to $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(10).

55. The purpose of the Anti-Kickback Statute is to ensure proper medical treatment and referrals, and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services.

56. Paying kickbacks taints an entire prescription, regardless of the medical necessity and/or the propriety of its use. The kickback inherently interferes with the doctor-patient relationship and creates a conflict of interest, potentially putting the patient's health at risk.

57. The Anti-Kickback Statute contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). However, none of the statutory exceptions or regulatory safe harbors protect the Defendant's conduct in this case.

58. In 2003, the HHS OIG issued its "Compliance Program Guidance for Pharmaceutical Manufacturers" (the "2003 Guidance"), which explained that "practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal health care program business," and that such practices would be illegal if "any

one purpose of the remuneration [is] to induce or reward the referral or recommendation of business payable in whole or in part by a federal health care program. Importantly, a lawful purpose will not legitimize a payment that also has an unlawful purpose." *Id.* at 13, 14 (emphasis in original). The 2003 Guidance then identified several questions that should be asked to determine if a practice violates the Anti-Kickback Statute, including:

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making?
- Does it have a potential to undermine the clinical integrity of a formulary process?
- Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees?
- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

Id. at 1.

59. As set forth in this Complaint, the answer to each of these questions with respect to Novo's marketing of NovoSeven® is "Yes."

60. Recently, the Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), amended the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the False Claims Act. The PPACA also amended the statute's "intent requirement" to make clear that violations of the anti-kickback provisions, like violations of the False Claims Act, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." *Id.* at Sec. 6402(h).

61. Knowingly paying kickbacks to providers to prescribe a prescription drug on-label or off-label for individuals eligible to receive reimbursement for the drug from a federal government health program or causing others to do so, while certifying compliance with the Medicare Anti-Kickback Statute (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates municipal, state and federal False Claims Acts.

62. As detailed below, Novo's marketing of NovoSeven® repeatedly violated provisions of the Anti-Kickback Statute, which in turn violated the False Claims Act, because Novo's improper kickbacks and incentives induced physicians to prescribe NovoSeven® when they otherwise would not have done so. In turn, many of those prescriptions were paid for by Medicare, Medicaid and other government-funded health insurance programs.

E. THE CALIFORNIA INSURANCE FRAUDS PREVENTION ACT

63. The California Insurance Frauds Prevention Act prohibits the knowing employment of "runners, cappers, steerers or other persons to procure clients or patients ... to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer." Cal. Ins. Code § 1871.7(a). It also establishes liability for parties that violate "Section 549, 550, or 551 of the Penal Code...." Cal. Ins. Code § 1871.7(b).

64. California Penal Code § 549 makes it illegal for any firm or corporation to "solicit[], accept[],or refer[] any business to or from any individual or entity with the knowledge that, or with reckless disregard for whether" that individual or entity will present or cause to be presented any false or fraudulent claim for payment of a healthcare benefit.

65. California Penal Code § 550 makes it illegal for any firm or corporation to "[k]nowingly present or cause to be presented any false or fraudulent claim for the payment of a loss or injury, including payment of a loss or injury under a contract of insurance"; "[k]nowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim"; and "[k]nowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit." Cal. Penal Code §§ 550 (a)(1), (5), and (6).

66. California Penal Code § 550 also makes it illegal for any firm or corporation knowingly to present, or to assist or conspire to "[p]resent or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact": and to "[p]repare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact." Cal. Penal Code §§ 550 (b)(1), (2).

67. The legislative findings and declarations associated with the California Insurance Frauds Prevention Act make clear that the Legislature was concerned with healthcare fraud: "Health insurance fraud is a particular problem for health insurance policyholders. Although there are no precise figures, it is believed that fraudulent activities account for billions of dollars annually in added health care costs nationally. Health care fraud causes losses in premium dollars and increases health care costs unnecessarily." Cal. Ins. Code § 1871(h).

V. BACKGROUND INFORMATION ON HEMOPHILIA

68. Hemophilia refers to a family of inherited and acquired bleeding disorders where those affected lack certain proteins in their blood – called "factors" – necessary to clot off a bleed. Without one of these factors, patients with hemophilia can bleed uncontrollably from injuries that would naturally stop bleeding and heal over in a healthy person.

69. Hemophilia A or B is congenital and affects primarily males. It is estimated that about 1 in 10,000 people have hemophilia A or B or about 20,000 people in the U.S. in 2011.

70. Patients with hemophilia A have either no, decreased, or defective production of the blood clotting protein Factor VIII ("FVIII"). Those with hemophilia B have similar impairments with Factor IX ("FIX"). Hemophilia is categorized as "mild," "moderate," or "severe" depending on the activity of the affected clotting factor (FVIII or FIX) as a percentage of normal. Severe hemophilia is often associated with spontaneous bleeding (*i.e.*, bleeding in the absence of evident trauma or injury). Approximately 7 out of 10 hemophiliacs are categorized as "severe" and can require treatment to stop spontaneous bleeding several times per month.

71. Severe hemophilia usually becomes apparent in the first years of life – often when a child starts to move about independently. Hemorrhages often occur in the joints (particularly weight-bearing joints, such as knees and ankles). These joint bleeds can cause severe pain and often cause permanent damage and disability. Other mild, moderate or even life-or-limb threatening bleeds can occur in muscles, soft tissues, gastrointestinal tract, or even the brain. In addition, trauma, major surgery, and even tooth extractions and other minor surgical procedures require medical treatment to manage the associated bleeding.

72. Hemophilia is treated by intravenous administration of the deficient factor Patients with Hemophilia A or B are normally treated with FVIII and FIX respectively. Over

time, these patients may develop inhibitors to FVIII or FIX, which are antibodies that inactivate the infused factor. When a patient develops these inhibitors, he does not respond as well or at all to a FVIII or FIX infusion. When this occurs, usually the patient responds to NovoSeven® or FEIBA, Factor Eight Inhibitor Bypassing Agent, a Baxter product.

73. Children with hemophilia can develop joint and other musculoskeletal problems later in life due to bleeding into joints while they are still young and growing. Therefore, depending on the severity of the hemophilia, children may be prescribed a clotting agent for primary prophylactic use – meaning regularly timed doses over an indefinite period of time unrelated to bleeding episodes – to prevent the development of even a first joint bleed. Prophylactic use of clotting factor in adult patients with hemophilia without inhibitors is used to decrease the rate of spontaneous bleeding events.

74. As a 2012 article in the journal *Blood Transfusion* states, "[T]he case for prophylaxis in adults remains open to debate and perhaps the true answer is that there actually is no answer, because we have no evidence-based instruments to ascertain to what extent adults benefit from ongoing prophylaxis."[13]

75. Similarly, at the 55th American Society of Hemophilia Annual Meeting in January 2013, after presenting a review of current, evidence-based treatment approaches in hemophilia and continuing unmet needs, Dr. Neil Josephson was quoted by the medical website Medscape.com as stating, "One issue for adults is that there are no 'iron-clad' data similar to

[13] Massimo Franchini and Pier Mannuccio Mannucci, *Prophylaxis for adults with haemophilia: towards a personalised approach?*, BLOOD TRANSFUS, Apr. 2012; 10(2): 123-124.

those from the Joint Outcome Study or ESPRIT to demonstrate that a patient is going to have a better outcome on prophylaxis."[14]

VI. SPECIFIC ALLEGATIONS OF NOVO'S FALSE CLAIMS

A. FDA APPROVAL AND LIMITED INDICATIONS FOR NOVOSEVEN®

76. Novo is the manufacturer of NovoSeven®. NovoSeven® is a biosynthetic FVII agent indicated for the treatment of acute bleeding episodes in hemophilia A or B patients with inhibitors to FVIII or FIX. It is also approved for the reduction of bleeding during surgical procedures in these same patients. NovoSeven® currently has no medical indications from the Food and Drug Administration ("FDA") for prophylactic and high dose use in either children or adults.

77. Novo could not receive a prophylaxis indication from the FDA without an adequate, controlled study demonstrating that NovoSeven® is, in fact, safe and effective for that use.

78. While Novo wanted to increase sales from prophylactic use of NovoSeven®, it did not want to pay the costs or incur the associated loss from sales that a controlled clinical trial would entail. It also did not want to risk that the trial would show no benefit from this expanded indication. The company had already paid for the limited Konkle prophylaxis study, which the FDA deemed inadequate. Rather than rigorously proving that its drug is safe and effective for prophylaxis care, Novo used anecdotal evidence to market NovoSeven® for this unapproved use.

79. Similarly, Novo also wanted to increase NovoSeven® sales by promoting higher doses than the FDA had approved, but it did not want to risk study outcomes which could show that lower single doses for some patients was equally effective. Relator Siegel was in charge of

[14] Linda Brookes, MSc, and Neil C. Josephson, MD, *Prophylaxis in Adults: Discuss Options, Consider Lower Doses*, Medscape, January 23, 2014.

designing such study, which was killed by Novo in 2009 when the company realized the potential for loss of sales should the study show that lower doses worked as well or better than higher ones.

B. NOVO CAUSED FALSE CLAIMS TO BE SUBMITTED FOR NOVOSEVEN® VIA SEVERAL SCHEMES

1. Novo Marketed Prophylaxis As a Treatment Regimen and High Dose Therapy for the Acute Treatment of Bleeds

80. Relator Siegel began her tenure with Novo on or about January 2008. Relator Siegel's position with the Company was in clinical development. At Novo, like other pharmaceutical companies, the clinical development team or division is primarily responsible for developing clinical trial protocols for new drugs and new uses of existing drugs. Relator learned that while some of her duties at Novo included the development of trials, Novo had hired her primarily to assist in their formulation and implementation of the off-label marketing of NovoSeven® for adult and child prophylaxis and for the use of doses that were much higher than directed by the package insert.

81. Within a few weeks of her hire, on January 18, 2008, Dr. Siegel was invited to a marketing strategy meeting in Princeton, New Jersey, attended by Novo's Business Section including employees from marketing and medical affairs and a Director of Marketing from Switzerland. Dr. Siegel was invited to this strategy meeting as a new member of the organization and for her ideas regarding the development of Novo's overall hemophilia marketing strategy, including discussion of potential new agents. The strategy meeting was to identify areas where Novo could expand the sales of NovoSeven®. At the time, Novo anticipated the failure of the intracranial hemorrhage and trauma studies, which had been designed to support an expanded indication for NovoSeven® to treat post-surgical or traumatic

bleeding for patients without hemophilia. Even prior to this meeting, the off-label strategy for this use was determined not to have a significant impact on the "bottom line" because only a few doses were used per patient.

82. The January 18 sales meeting was organized by Paul Huggins, Senior Director of International Marketing at Novo. The meeting included Klaus Davidsen, Howard Levy, Gar Park, Michael Ferrara, Michael LaMotta, and David Cooper, all within business development and marketing or medical affairs, for Novo. The primary U.S. medical affairs personnel at Novo at the meeting was David Cooper, Novo's Director of Medical Affairs. Howard Levy, Cooper's manager, was responsible for clinical development, medical affairs, and regulatory affairs ("CMR"), holding the title of Executive Director of CMR. Though Medical Affairs was ostensibly organized to respond to questions or concerns from treating physicians, Novo's Medical Affairs Division was primarily engaged with marketing.

83. New to Novo at the time, Relator Siegel was under the impression that the January 18 meeting was intended to cover areas for new research and trials. It quickly became apparent to Relator Siegel, however, that the purpose of the meeting was primarily to discuss new marketing strategies for NovoSeven®. This focus on the expansion of NovoSeven® into off-label uses continued for the duration of Relator Siegel's employment and it continues today. Relator Siegel was asked during the meeting to suggest new research areas to explore. She later learned that her input on potential new research areas was used, instead, to develop new marketing strategies for NovoSeven®, in particular, prophylaxis.[15]

[15] During this meeting Novo's Paul Huggins used a diagram that showed the "expanded pipeline," for NovoSeven®. It is featured in Novo's 2009 Annual Report and shows Novo's marketing plan. Novo has received no new indications since 2009, instead expanding their market through off-label promotion.

84. On February 5, 2008, a summary memorandum of the January 18 strategy meeting was distributed to the meeting attendees. The email – with the subject line "Haemoophilia [sic.] Portfolio Strategy Workshop" – noted that the key new marketing opportunities included prophylaxis for adults and children. The attached memorandum contained an entire segment entitled "identify opportunity space," which listed five marketing segments deemed to be the "most lucrative." These marketing segments included prophylaxis for adults without factor inhibitors and children both with and without factor inhibitors. The notes to the "opportunity space" section explained that particular attention was to be given to initiating prophylaxis in children and following through with them to adulthood, "when they start to make [their] own decisions regarding therapy choice[s]."

85. The summary memorandum predicted hemophilia treatment trends, which included dramatic increases in prophylaxis among children and adults. The treatment trends discussion noted ways to maintain patients on prophylactic treatment regimens by reaching out to insurance providers to ensure continued coverage for treatment and managing life-time insurance caps.

86. The memorandum also discussed ways to make prophylactic treatment more attractive to potential patients by developing a long-acting form that required fewer dose administrations throughout the day. The memorandum also discussed marketing strategies for pulling NovoSeven® off the market once its patent expired and replacing it with a drug labeled NN1731, purported to work faster and better but which failed in clinical trials, as a way to maintain patent protection against generics in the prophylactic treatment market.

87. While many of the ideas discussed above may sound like novel and useful product improvements for Novo, it is important to remember that this was a marketing meeting.

Novo was finding new ways to market NovoSeven® and expand into other treatment areas in hemophilia either with new drugs or with NovoSeven® which was indicated only for acute "on demand" treatments, not prophylaxis. Indeed, the memorandum notes that one of the "challenges" to the Novo's marketing strategies was the "increasing regulatory scrutiny (FDA)."

88. During her tenure, Relator was involved in many Novo marketing meetings designed to implement the marketing strategy laid out in the February 5 memorandum, including the "Prophylaxis War Games," a reference to Novo's attempt to capture the inhibitor patients who were using Baxter's FEIBA (a competitor to NovoSeven®) for prophylaxis off-label.[16] It was not until 2014, that the FDA approved FEIBA for prophylaxis for adults and adolescents.

89. The prophylaxis war games and other marketing initiatives, including Novo's PRO-PACT prophylaxis study (which nothing more than a case study review of 86 patients), were also discussed in an internal Novo memorandum dated April 2009, which indicates that Novo intended to utilize such "strategic brand plan processes" for two to five years.

90. After the January 18, 2008 meeting, Relator Siegel was invited to attend another Novo marketing meeting in Switzerland, called the "Zurich Task Force Group 'Prophylaxis Initiative.'" She inquired why she was included especially because the meeting seemed to be more a matter for Medical Affairs, which was the responsibility of David Cooper. Dr. Siegel was at that time working on many projects within clinical development that required attention and oversight. Nonetheless, she was told apologetically by her supervisor, Howard Levy that she needed to attend because of her U.S. hemophilia experience.

91. The reason for her inclusion became evident only when she returned from the meeting and received a follow-up call from two Novo physicians from the meeting in Zurich; she

[16] Relator has a calendar that memorializes many of these meetings.

was told that she was expected to use her relationships to find physicians in the U.S. to author publications for Novo promoting off-label use of NovoSeven®.[17] According to the participants in the meeting in Zurich, such publications would be used to counteract the adverse decision by the FDA with regard to the expanded use of NovoSeven® for prophylaxis. So once the FDA denied Novo's requests for a prophylaxis and high dose indications, Novo's marketing efforts were focused on identifying physicians who had used or would use NovoSeven® for prophylaxis and publish the results.

92. The 2008 meeting in Zurich included Novo Medical Affairs representatives from all the relevant countries/regions. At the time, for example, the NovoNordisk representative from Spain had already identified an investigator who was willing to have his experience using NovoSeven® for prophylaxis written and published. Repeatedly during this meeting, the focus for this prophylaxis initiative was to identify the "low hanging fruit," or physicians who were willing to provide case reports for publication promoting the benefits of prophylaxis. After the Zurich meeting and follow-up call with the physicians leading the meeting, Relator Siegel informed her boss, Howard Levy, that she was not willing to identify and encourage physicians to write articles on prophylactic use of NovoSeven®.

93. After Relator's meeting with Levy, Novo asked Dr. Cooper to carry out this assignment instead, which he did, working with other Novo employees. Dr. Cooper is a co-author of many off-label NovoSeven® articles ultimately published in top hemophilia journals, which continue to be published to this day.

[17] Relator believes this meeting may have occurred on March 6, 2008 as her calendar from her tenure at Novo states "meeting to discuss prophy [prophylaxis] patients."

2. Novo Engaged In Off-Label Marketing and Paid Kickbacks to Physicians Through The HTRS Registry

94. Instead of commissioning legitimate studies to obtain an indication for prophylactic use, Novo found a quick and dirty way to produce "scholarly" articles on high dose and prophylactic use of its product to manipulate physician opinions through the Hemostasis and Thrombosis Research Society ("HTRS") Registry, which was created by Novo – via the third party HTRS – to comply with FDA post-marketing data collection requirements for NovoSeven®.

95. The HTRS is a research group set up by Novo to collect information on patients with any form of hemophilia from their treating physicians. According to the HTRS website, at the time NovoSeven® was approved for sales, "the FDA required a system of post-licensure monitoring for adverse events to capture safety and efficacy information on patients treated with NovoSeven®. The HTRS registry became this platform, capturing information on treatment of bleeding episodes and during surgeries in congenital hemophilia, congenital factor VII deficiency, and acquired hemophilia ...." among other things. The registry, however, morphed into a repository of clinical data on off-label uses from which Novo could cherry pick and produce propaganda pieces disguised as scholarly articles advocating widespread use of NovoSeven® for prophylaxis and at higher doses than the FDA had approved.

96. Each physician or treatment center that enrolled in the HTRS registry was required to enter into an agreement with Novo on the collection and use of information for the registry. Per the contract, in exchange for generous financial rewards, any time Novo wished to sponsor a research study, all participating doctors or treatment centers were to identify "all of its patients that are eligible for participation in such [s]tudy" and recruit those patients for participation. The physician or treatment center was to then collect the patient's information for

the study and put it into the HTRS registry website per the study's requirements. The contract specifically stated that while the individual treatment centers were allowed to use the information they collected for their own purposes, including publication, they could only do so with prior written consent from HTRS. HTRS, however, was entitled to use all the data submitted to it for its own purposes, "including, without limitation, publication," without the consent of any of the participating treatment centers or doctors.

97. The financial incentives to physicians offered by Novo through the registry were generous. First, HTRS provided a $1,500 grant to any new participant to purchase a new computer to use for the registry. The computer was the property of the participant and came with no restrictions other than adequate hardware to participate in the registry. HTRS then paid each participant a "startup grant" of $1,000. Each participant was also paid for the data collected on patients and submitted to HTRS. The contract lists a schedule in the back with payment rates for various data collections, including $100 for each new patient registration and $100 for each "acute bleed form" documenting a bleeding event. Participants were further incentivized with volume bonuses for entering bleed data into the Registry. For every 10 bleeding events entered into the Registry per quarter, the participating treatment center or physician was paid a bonus of $1,000. While the contract states that these payments are "data entry grants" designed to "offset the cost of entering bleed data into the Registry," these payments effectively served as kickbacks for participants to enroll as many patients as possible in the registry. The contract notes that Novo provides the financial support for the Registry and that payments to physicians will continue as long as Novo provides such funding. NovoSeven® was approved by the FDA in 1999, and Novo provided continuous funding to the HTRS Registry until it was closed recently.

98. Because the Registry provides a wealth of data for Novo to use for off-label promotion, Novo worked hard to collect data from HTRS Registry participants. In some instances where a treatment center or physician was slow to input data or otherwise indifferent to participation, Novo provided a paid study coordinator to enter information for them, and continue to award bonuses for participation.

99. Novo began this by offering kickbacks to physicians, by way of the HTRS registry database by paying them to enter patients in a post-marketing study for continued surveillance required by the FDA. This registry "safety" study became a vehicle for the sales force to encourage off-label prescriptions for high dose and prophylaxis by physicians. There was an initial payment and then a further payment associated with every documented NovoSeven® use and entry. The Novo sales force and Medical Science Liaisons also offered to have Novo Nordisk employees "write up" positive reports about patient outcomes on behalf of the physician who had prescribed NovoSeven®. Even before Relator's time at Novo she was aware of the practices described above. When Relator was the Director of the Cardeza Hemophilia Center at Thomas Jefferson Hospital in Philadelphia, a NovoSeven® sales representative encouraged Relator to enter her patients into the registry and told Relator if she was too busy to enter the data, Novo would pay for a coordinator to enter the required information. The sales representative also told Relator that she could enjoy the added benefit of having Novo write a "case study" from the data, which could be submitted to a medical journal for publication. Relator refused and, on a subsequent visit, told the representative not to return to her office. As described above, Relator later learned that such marketing tactics were centrally devised by Novo and communicated to all its sales representatives.

100. The use of data required by FDA post-marketing surveys by drug companies to market drugs off-label or to tout safety or efficacy characteristics not approved by the FDA is not uncommon and is still unlawful despite the Government's request for data collection. For example, a 2012 article published by an anonymous drug company employee in the British Medical Journal details the efforts of a major drug company to use "observational" data to market drugs through various efforts, including paying or offering valuable remuneration to key opinion leaders to deliver marketing messages not approved by the FDA and publishing articles highlighting such uses.[18]

3. Novo Engaged In Off-Label Marketing Through HTRS Articles and CMEs

101. Once the HTRS Registry collected data on off-label NovoSeven® prescriptions for prophylaxis or high dose prophylactic use, Novo commissioned a "scholarly" article or a Continuing Medical Education ("CME") seminar on the topic.

102. Novo often used the Blood CME Center, which sponsored some of its CME seminars, as a conduit to market its off-label prophylaxis message. For example, in or about August 7, 2013, Novo sponsored a CME through Blood CME Center entitled "Hemophilia Experts Video Summit: How We Manage the Musculoskeletal Complications of Hemophilia in Pediatric Patients." The abstract for the CME states that its educational objectives include "[d]iscuss[ing] current evidence-based data and expert opinion on the use of prophylaxis in hemophilia patients . . . . Describ[ing] trends and emerging issues relevant to prophylactic treatment of patients with or at risk for developing inhibitors. Discuss[ing] the prophylactic . . . use of bypassing agents in pediatric patients . . . and [instructing doctors on how to] [p]rovide

[18] *Post-Marketing Observational Studies: My Experience in the Drug Industry*, BMJ, June 12, 2012.

appropriate counsel and education for patients and their families about prophylaxis . . . ." This CME is hardly unique; in or about September 18, 2013, Novo sponsored a CME entitled "Prophylactic Bypassing Therapy in Pediatric Inhibitor Patients to Avoid Musculoskeletal Complications." Each of these CMEs, paid for by Novo, included among educational objectives: on instructing doctors on prophylaxis as a treatment regimen and how to counsel families and patients on accepting and using prophylaxis as a treatment regimen.

103. Novo also frequently wrote puff pieces backed by HTRS Registry data and asked physicians to sign on as co-authors who had little or no input into the article. These articles substituted anecdotal facts for legitimate study data to support off-label uses promoted by Novo. At internal meetings, David Cooper discussed data from the HTRS registry that was later used to publish articles. Relator was asked to review abstracts before they were presented at scientific meetings; this data was later used to publish manuscripts promoting the use of NovoSeven® in high doses and for prophylaxis. She was aware that these abstracts were scientifically insufficient to support any of the uses discussed, yet were later published using these physicians' names. She reported this concern to her supervisor Howard Levy, but he was powerless to stop the production and publication of these articles.

104. Novo sponsored "consensus meetings" or "roundtable discussion meetings" where experts selected by Novo were to "collaborate" on best practices. Each roundtable participant was paid travel and honoraria expenses by Novo: Novo coordinated the meeting and assigned topic areas to each of the participating experts in order to control the outcome and recommendations of the meeting. Some of the hemophilia physicians participating in these roundtable discussion meetings were also designated as KOLs by Novo. Novo paid KOLs not only to participate in roundtable discussions and lend their names to articles written or co-

authored with Novo employees but to influence other health care professionals treating hemophilia patients.

105. Novo has paid for and written multiple articles from 2009 to the present, authored by David Cooper and other Novo employees and consultants with KOLs. Many of these articles promoted off-label prophylaxis and high doses of NovoSeven® and were published in *Haemophilia*, the official journal of the World Federation of Hemophilia and HTRS, whose editor, Craig Kessler, is a Novo KOL. In many cases, Cooper and other Novo employees mined the data from the HTRS registry and wrote articles purportedly authored by KOLs or other influential hemophilia physicians.

106. For example, the following articles promoting the of NovoSeven® for prophylaxis were generated in this way:

- A Shapiro, *Inhibitor treatment; state of the art*, Semin Hematol, Oct. 2001, at 26-34
- WK Hoots, LS Ebbesen, BA Konkle, GK Auerswald, HR Roberts, J. Weatherall, JM Ferran, RC Ljung and Novoseven (F7HAEM-1505) Investigators, *Secondary prophylaxis with recombinant activated factor VII improves health-related quality of life of haemophilia patients with inhibitors*, Haemophilia, May 2008, at 14(3):466-75
- G. Young, G. Auerswald, V. Jimenez-Yuste, BA Konkle, T. Lambert, M. Morfini, E. Santagostino and V. Blanchette, *When should prophylaxis therapy in inhibitor patients be considered?*, Haemophilia, Sept. 2011, at 17(5):e849-57
- G. Young, G. Auerswald, V. Jimenez-Yuste, T. Lambert, M. Morfini, E. Santagostino and V. Blanchette, *PRO-PACT: retrospective observational study on the prophylactic use of recombinant factor VIIa in hemophilia patients with inhibitors*, Thromb Res., Dec. 2012, at 130(6):864-70
- RA Gruppo, CM Kessler, EJ Neufeld and DL Cooper, *Assessment of individual dose utilization vs. physician prescribing recommendations for recombinant activated factor VII (rFVIIa) in paediatric and adult patients with congenital haemophilia and alloantibody inhibitors (CHwI): the*

Dosing Observational Study in Hemophilia (DOSE), Haemophilia, July 2013, at 19(4):524-32

- AD Shapiro, EJ Neufeld, V. Blanchette, P. Salaj, RZ Gut and DL Cooper, *Safety of recombinant activated factor VII (rFVIIa) in patients with congenital haemophilia with inhibitors: overall rFVIIa exposure and intervals following high (>240 μg kg^{-1}) rFVIIa doses across clinical trials and registries,* Haemophilia, Jan. 2014, at 20(1):e23-31

- J. Maahs, J. Donkin, M. Recht and DL Cooper, *Mixing and administration times of bypassing agents: observations from the Dosing Observational Study in Hemophilia (DOSE),* J Blood Med, Aug. 20, 2014, at 5:153-6

- M. Recht, EJ Neufeld, VR Sharma, CT Soloem, *AS Pickard, RZ Gut and DL Cooper, Impact of acute bleeding on daily activities of patients with congenital hemophilia with inhibitors and their caregivers and families: observations from the Dosing Observational Study in Hemophilia (DOSE),* Value Health, Sept. 17, 2014, at (6):744-8

107. Likewise, Novo also generated the following articles, which were designed to promote a single high dose of NovoSeven®, which is not indicated drug's package insert.

- AD Shapiro, *Recombinant factor VIIa in the treatment of bleeding in hemophilic children with inhibitors,* Semin Thromb Hemost, 2000, at 26(4):413-9

- A Shapiro, *Inhibitor treatment; state of the art,* Semin Hematol, Oct. 2001, at 38(4 Suppl 12):26-34

- S. Seremetis, *Dose optimization of recombinant factor VIIa in the treatment of acute bleeding in haemophilia-associated inhibitors,* Blood Coagul Fibrinolysis, June 2003, at 14 Suppl 1:S29-30

- TC Abshire, *Dose optimization of recombinant factor VIIa for control of mild to moderate bleeds in inhibitor patients: Improved efficacy with higher dosing,* Semin Hematol, Jan. 2004, at 41(1 Suppl 1):3-7

- R. Parameswaran, AD Shapiro, JC Gill, CM Kessler and HTRS Registry Investigators, *Dose effect and efficacy of rFVIIa in the treatment of haemophilia patients with inhibitors: analysis from the Hemophilia and Thrombosis Research Society Registry,* Haemophilia, Mar. 2005, at 11(2):100-6

- G. Kenet, *High-dose recombinant factor VIIa therapy in hemophilia patients with inhibitors,* Semin Hematol, Jan. 2006, at 43(1 Suppl 1):S108-10

- G. Kenet and U. Martinowitz, *Single-dose recombinant activated factor VII therapy in hemophilia patients with inhibitors*, Semin Hematol, Apr. 2008, at 45(2 Suppl 1):S38-41

- AD Shapiro, *Single-dose recombinant activated factor VII for the treatment of joint bleeds in hemophilia patients with inhibitors,* CLIN ADV Hematol Oncol, Aug. 2008 at 6(8):579-86

- T. Abshire and G. Kenet, *Safety update on the use of recombinant factor VIIa and the treatment of congenital and acquired deficiency of factor VIII or IX with inhibitors,* Haemophilia, Sept. 2008, at 14(5):898-902

- C. Nakar, DL Cooper and D. DiMichele, *Recombinant activated factor VII safety and efficacy in the treatment of cranial haemorrhage in patients with congenital haemophilia with inhibitors: an analysis of the Hemophilia and Thrombosis Research Society Registry (2004-2008),* Haemophilia, July 1, 2010, at 16(4):625-31

- EJ Neufeld, CM Kessler, JC Gill, CT Wilke, DL Cooper and HTRS Investigators, *Exposure and safety of higher doses of recombinant factor VIIa ≥250 μg kg(-1) in individuals with congenital haemophilia complicated by alloantibody inhibitors: the Haemophilia and Thrombosis Research Society Registry experience (2004-2008,)* Haemophilia, Jul. 2011, at 17(4):650-6

- G. Young, AD Shapiro, CE Walsh, RA Gruppo, RZ Gut and DL Cooper, *Patient/caregiver-reported recombinant factor VIIa (rFVIIa) dosing: home treatment of acute bleeds in the Dosing Observational Study in Hemophilia (DOSE),* Haemophilia, May 2012, at 18(3):392-9

- G. Young, DL Cooper, RZ Gut and HTRS Investigators, *Dosing and effectiveness of recombinant activated factor VII (rFVIIA) in congenital haemophilia with inhibitors by bleed type and location: the experience of the Haemophilia and Thrombosis Research Society (HTRS) Registry (2004-2008),* Haemophilia, Nov. 2012, at 18(6):990-6

- RA Gruppo, CM Kessler, EJ Neufeld and DL Cooper, *Assessment of individual dose utilization vs. physician prescribing recommendations for recombinant activated factor VII (rFVIIa) in paediatric and adult patients with congenital haemophilia and alloantibody inhibitors (CHwI): the Dosing Observational Study in Hemophilia (DOSE)*, Haemophilia, Jul. 2013, at 19(4):524-32

- EJ Neufeld, K. Saxena, CM Kessler, DL Cooper & HTRS Investigators, *Dosing, efficacy, and safety of recombinant factor VIIa (rFVIIa) in pediatric versus adult patients: the experience of the Hemostasis and*

Thrombosis Research Society (HTRS) Registry (2004-2008). Pediatr Blood Cancer, Jul. 2013, at 60(7):1178-83

- AD Shapiro, EJ Neufeld, V. Blanchette, P. Salaj, RZ Gut and DL Cooper, *Safety of recombinant activated factor VII (rFVIIa) in patients with congenital haemophilia with inhibitors: overall rFVIIa exposure and intervals following high (>240 μg kg^{-1}) rFVIIa doses across clinical trials and registries,* Haemophilia, Jan. 2014, at 20(1):e23-31

108. Not one of these articles resulted from a blinded, randomized, controlled study, which is the "gold standard," used by the FDA to approve drugs. Instead these articles were generated from data from the HTRS registry and/or other "case reports," which are nothing more than anecdotal accounts of treatment outcomes experienced by one or a few patients with hemophilia with inhibitors.

109. Indeed Relator Siegel was tasked at Novo with reviewing and commenting on early abstracts for some of the articles noted above as well as to review some of the manuscripts that had already been generated by Novo before or immediately after her arrival, such as the 2008 article by Dr. Hoots *et al.* entitled, "Secondary prophylaxis with recombinant activated factor VII improves health-related quality of life of haemophilia patients with inhibitors." When Relator Siegel reviewed the abstract for this article, she informed Novo that the quality of life data presented did not meet relevant scientific standards and should not have been published.

110. Other articles listed above were written primarily or exclusively by Novo employees, including physicians and non-physicians alike, many of whom had no educational background or experience in hemophilia. For example, Dr. Cooper had been in a neurosurgery residency program and then acquired an MBA prior to being hired by Novo to market NovoSeven®.

111. Moreover, Relator detected key Novo marketing messages in some of the articles, which are rife with words not used in legitimate scientific journal articles, such as the phrase,

"optimization of dosing regimens may be achieved by considering..." contained in the 2001 Shapiro article entitled, "Inhibitor treatment; state of the art." This phrase was one of Novo's key off-label messages regarding high doses and prophylaxis.

C. NOVO OFFERED KICKBACKS TO ENCOURAGE PROPHYLACTIC USE OF NOVOSEVEN®

112. In addition to paying physicians to submit information to the HTRS Registry and write or sign "studies" written or edited by Novo to support off-label uses of NovoSeven®, Novo also paid KOLs to write more prescriptions and influence prescription writing of other physicians.

113. The KOL kickback program was developed during Relator's tenure at the company. As part of these efforts, Novo's marketing department developed, *inter alia*, a KOL plan and a small glossy booklet, summarizing important information about each KOL, to assist Novo sales representatives and other marketing professionals when marketing NovoSeven® to other professionals or when entertaining the KOLs.

114. For example, KOLs were sent to all expenses paid roundtable discussions and other more exclusive high-level meetings where Novo ostensibly sought their experience with NovoSeven® and "guidance" for future uses. In reality, Novo showered money and other remuneration on the KOLs so that they would use or continue to use large quantities of NovoSeven® either by recommending prophylaxis to their patients or prescribing high doses. An added benefit to the payments made to KOLs was that Novo could use their prescribing habits to convince other doctors to use NovoSeven® in the same ways.

115. For example, Relator who was not a KOL, was invited by Novo in 2001 to a symposium in Copenhagen at which she was reimbursed for her travel and lodging and was paid an honorarium of about $5,000 to learn about off-label uses for NovoSeven®. The symposium

was predominately about NovoSeven®'s expected use for trauma surgery for non-hemophilia patients[19] and CNS bleeding, but also included lecture of prime importance to the community of hemophilia physicians by Dr. Gilit Kenet who presented her limited data on the use of "megadose" NovoSeven® to control bleeding episodes in a few of her pediatric patients with hemophilia and inhibitors. This was the first time that Relator had learned about Novo's intent to market NovoSeven® in doses that were larger than indicated by the package insert. The purpose of the payments and remuneration were not only to secure prescriptions but also served as an off-label marketing vehicle for Novo.

116. Likewise, in one three month period in 2013, Novo paid its KOL, Dr. Craig Kessler, over $34,000 in expenses, honoraria, and other remuneration. Dr. Kessler is also a Professor at Georgetown University Medical Center in the Departments of Medicine and Pathology *and* Chair of the Medical and Scientific Advisory Council ("MASAC") for the National Hemophilia Foundation. During these three months in 2013, MASAC released guidance promoting the use of bypassing agents for prophylaxis, including NovoSeven®. With regard to prophylaxis use of NovoSeven®, the MASAC guidance relies on a study of NovoSeven® by Dr. Barbara Konkle that was rejected by the FDA years ago.

D. NOVO OFF-LABEL MARKETED NOVOSEVEN® TO PATIENTS THROUGH INHIBITOR CAMPS AND ADULT PATIENT WEEKEND RETREATS

117. Novo markets NovoSeven® off- label directly to patients and their families for adult and child prophylaxis through a number of recurring marketing events, designed and paid for by the company, which were ostensibly advertised as educational events, including "weekend summits" for adults with hemophilia and inhibitors and "inhibitor camps" for children. These

[19] This off-label use was the subject of Novo's 2011 False Claims Act settlement of over $25 million.

summits and camps were advertised or offered by Novo directly or through patient advocacy groups and hemophilia vendors operating under the aegis of Novo. At these events, prophylaxis – among other therapies – is promoted to patients and their families and caregivers.

118. For example, the National Hemophilia Foundation ("NHF") advertised on its website a "2009 Inhibitor Education Summit," which indicates that one the key topics to be discussed by the speakers is "current management options for patients with hemophilia and inhibitors, such as prophylaxis..." Specifically, the agenda indicates that "Prophylaxis with Bypassing Agents," will be discussed for patients registering for events designated as "Track 1: Hemophilia with Inhibitors 101." The agenda for "Track 3: Young Men – Hemophilia with Inhibitors," is a discussion about "Early Treatment of Bleeding and Prevention of Joint Disease." The terms "early treatment" and "prevention," were and are used by Novo as promotional terms to enhance their message to self-infuse more often, at higher doses, and as prophylaxis.

119. Indeed, the Novo Nordisk label is prominently displayed on the first page of the Inhibitor Education Summit web advertisement, with words indicating that the event was "supported by an educational grant from Novo Nordisk." Though Baxter also manufactures a bypassing agent, FIEBA, the Inhibitor Summit appears to have received no support from Baxter. Indeed, the two Co-Chairs for this particular summit were Dr. Leonard Valentino and Dr. Guy Young, who were Novo KOLs.

120. In addition to funding the Inhibitor Summit, Novo (with the message delivered by NHF) also attempts to influence patients (and their caregivers) by paying them to attend the event. For example, the advertisement indicates that "travel grants are available," for patients and their families covering the cost of travel (including air fare), lodging and on-site. The two events in 2009 were held in Washington, D.C. and Hollywood, California during the summer.

Free child care at these events was also provided. In Relator's experience, such perks are a powerful influence for individuals with hemophilia.

121. Novo also recruits charismatic patients with hemophilia and inhibitors to help convey its off-label marketing messages at summits and camps for patients with inhibitors. For example, an on-line newsletter reporting on the events of a 2007 inhibitor summit in San Diego, indicates that [redacted], a patient with hemophilia and inhibitors, attended the summit as well as Novo KOL, Dr. Guy Young, and a Novo marketing employee, Ms. Gar Park. [redacted] was also on the Steering Committee of the NHF 2009 Summit discussed above.

122. Novo has also featured in [redacted] in educational literature disseminated to patients by Novo. [redacted] uses/discussed his use of NovoSeven® in prophylaxis and is/was paid by Novo to attend and speak on behalf of the company.

123. While Novo has paid for similar summits and camps since at least 2005, in 2007 Novo transitioned some of its direct to patient marketing events, such as the inhibitor camps and summits, to NHF by issuing a sham "Request for Performance." At this time, the Hemophilia Federation of America ("HFA"), another hemophilia advocacy group, believed HFA could also bid on these Novo marketing events in partnership with NHF, but the Relator soon learned that Novo had never intended to have HFA involved. By securing NHF to assist in its marketing, Novo was able to disguise its unlawful marketing tactics.

124. To this day, Novo still supports a myriad of all-expense paid marketing events, similar to the Inhibitor Summit described above. For example, Novo is the sole sponsor of an Inhibitor Family Camp, marketed by Comprehensive Health Education Services, L.L.P. ("CHES"), held in the summer of 2012 at the Rocking Horse Ranch Resort Center in New York. Indeed, while CHES purports to be an education resource for patients with hemophilia, its

website indicates that its two founders are long time industry advocates.[20] CHES was founded in 2009 by Janet Brewer and Eric Lowe. Ms. Brewer served on Novo's "Consumer Council" from 2009 to 2011, concurrently during her tenure at CHES, and was a past director of educational programing for a "small home health care" company selling clotting factor to patients with hemophilia. CHES's website likewise notes that Mr. Lowe, who suffers from hemophilia with inhibitors, is often "featured as an advocacy resource for companies in the bleeding disorder industry." At the CHES camp, there is no need to apply for a grant because everyone attends free, air fare is arranged, all travel expenses are reimbursed and all meals are provided.

E. HARMS ASSOCIATED WITH THE USE OF NOVOSEVEN® FOR PROPHYLAXIS OR IN HIGH DOSE REGIMENS

125. The use of NovoSeven® in prophylaxis and in high doses is not benign. Indeed, the package insert FDA warns of increased risks of thrombosis, that is, clots where they should not occur, when NovoSeven® is used off-label. In a black box warning, the FDA emphasizes: **"Safety and efficacy of NovoSeven RT has not been established outside the approved indications."** (Emphasis in the original.) In Section 5.3 of the label, FDA advises that "Precautions should be exercised when NovoSeven® RT is used for prolonged dosing", with a reference to Section 2.2, which states that: "the biological and clinical effects of prolonged elevated levels of Factor VIIa have not been studied; therefore, the duration of post-hemostatic dosing should be minimized."

[20] *See* www.compheathcd.com.

126. Additionally, the FDA published a JAMA article in 2006[21] reviewing the 185 thromboembolic adverse events associated with Novo 7 that had been reported to the agency's Adverse Event Reporting System ("AERS") from March 1999, when NovoSeven® was first approved, through December 31, 2004. Since AERS is a voluntary system of reporting, the FDA notes that its database likely undercounts the true number of thromboembolisms. Nevertheless, while 151 of the 185 thrombotic events involved non-hemophilia patients using NovoSeven® off-label, there were several hemophilia patients that experienced thrombotic events as well, indicating that patients with congenital hemophilia using NovoSeven® are not without risk.

127. There is another serious safety problem associated with using NovoSeven® for prophylaxis and in high doses. All factors are administered intravenously and for some patients that requires an indwelling line or catheter. The catheter itself increases the risk of thrombosis and this is compounded by the infusion of a bypassing agent such as NovoSeven®, particularly if given in high doses or on a continuous basis as with prophylaxis. Moreover all these lines must still go through the skin, which is covered with bacteria. If care is not meticulous at all times, bacteria can move down the central line and enter the systemic circulation, causing serious infection. The longer a line is in, the more often it is accessed, the higher the risk of infection.

128. By promoting NovoSeven® off-label for prophylaxis and in high doses, Novo is putting patients who already suffer from a debilitating disease at serious risk without any proven prospect of benefit.

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[21] *See* O'Connell, Kathryn A. et al., *Thromboembolic Adverse Events After Use of Recombinant Human Coagulation Factor VIIa*, JAMA, January 18, 2006 - Vol. 295, No. 3.

VII. COUNTS

COUNT ONE
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)[22]

129. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

130. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

131. By virtue of the misrepresentations, off-label promotion, kickbacks, and submissions of non-reimbursable claims described above, Defendant knowingly presented, or caused to be presented, false or fraudulent claims for improper payment or approval of prescriptions for Novo7.

132. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

133. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWO[23]
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B)

134. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

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[22] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730(a)(1) (1986).

[23] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730(a)(2).

135. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

136. By virtue of the misrepresentations, off-label promotion, kickbacks, and submissions of non-reimbursable claims described above, Defendant knowingly made, used, or caused to be made or used, a false record(s) or statement(s) material to a false or fraudulent claim with regard to prescriptions for Novo7.

137. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

138. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

COUNT THREE
California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*

139. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

140. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*

141. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the California Medicaid Program (*i.e.*, Medi-Cal) false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

142. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the California False Claims Act.

143. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

144. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT FOUR
California Insurance Frauds Prevention Act,
Cal. Ins. Code § 1871.7

145. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

146. This is a claim for treble damages and civil penalties under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7.

147. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant caused to be presented, or knowingly assisted or conspired in presenting or causing to be presented, to the insurers in the State of California fraudulent claims that were induced by payments of kickbacks to physicians, in violation of California Penal Code § 550(b)(1), among other provisions.

148. Moreover, by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be made fraudulent bills intended to be presented to the insurers in connection with, or in support of, claims for the payment of compensation under contracts of insurance knowing that the statements contained false or misleading information concerning material facts, in violation of California Penal Code § 550(b)(2), among other provisions.

149. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented false or fraudulent claims for the payment of a loss or injury, including payment of a loss or injury under a contract of insurance; prepared, made, and subscribed writings, with the intent to present or use it, or to allow it to be presented, in support of false or fraudulent claims; and made or caused to be made false or fraudulent claims for payment of a health care benefit in violation of California Penal Code § 550(a)(1), (5), and (6), among other provisions.

150. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant caused false claims to be submitted to insurance companies for the payment of health care benefits. Had the private insurance companies known that prescriptions for Defendant's drugs had been written because physicians had been paid kickbacks by Defendant to do so and/or that Defendant had made statements containing false or misleading information concerning facts material to such prescriptions, these companies would not have provided reimbursement for these prescriptions.

151. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant's conduct represents the inducement of health care benefits through a pattern and practice of fraudulent conduct and constitutes false claims within the meaning of Cal. Ins. Code § 1871.7(b) and Sections 549 & 550(a)(6) of the California Penal Code, among other provisions.

152. By reason of these payments, insurers have been damaged, and continue to be damaged, in a substantial amount.

COUNT FIVE
Colorado Medicaid False Claims Act,
Colo. Rev. Stat. §§ 25.5-4-303.5, et seq.

153. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

154. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5, *et seq.*

155. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Colorado Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

156. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Colorado False Claims Act.

157. The Colorado Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

158. By reason of these payments, the Colorado Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT SIX
Connecticut False Claims Act,
Conn. Gen. Stat. §§ 17b-301a -17b301p (2010 Supplement)[24]

159. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

160. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. §§ 17b-301a - 17b-301p (2010 Supplement).

161. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Connecticut Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

162. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Connecticut False Claims Act.

163. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

164. By reason of these payments, the Connecticut Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

[24] Connecticut General Statute §§ 17b-301a-17b301p was repealed by the legislature by Public Act No. 14-217, effective July 1, 2014, and was replaced by an expanded version of the Connecticut False Claims Act, but the expanded version has not yet been codified. *See* http://www.cga.ct.gov/2014/act/pa/pdf/2014PA-00217-R00HB-05597-PA.pdf.

COUNT SEVEN
Delaware False Claims And Reporting Act, 6 Del. Code §§ 1201 *et seq.*

165. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

166. This is a claim for treble damages and civil penalties under the Delaware False Claims And Reporting Act, 6 Del. Code §§ 1201 *et seq.*

167. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Delaware Medicaid program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

168. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Delaware False Claims Act.

169. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

170. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT EIGHT
Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 *et seq.*

171. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

172. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 *et seq*.

173. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Florida Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

174. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Florida False Claims Act.

175. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

176. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT NINE
Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 *et seq*.

177. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

178. This is a claim for treble damages and civil penalties under the Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 *et seq*.

179. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Georgia Medicaid Program false or fraudulent claims for payment or approval and/or

knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

180. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Georgia False Medicaid Claims Act.

181. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

182. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TEN
Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*

183. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

184. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*

185. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using or causing to be made or used, a false record or statement.

186. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Hawaii False Claims Act.

187. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

188. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT ELEVEN
Illinois False Claims Act,
740 Ill. Comp. Stat. 175/1 *et seq*.

189. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

190. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1 *et seq*.

191. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Illinois Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

192. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Illinois Whistleblower Reward and Protection Act.

193. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

194. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWELVE
Indiana False Claims and Whistleblower Protection Act,
Ind. Code §§ 5-11-5.5-1 *et seq.*

195. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

196. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1 *et seq.*

197. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Indiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

198. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Indiana False Claims and Whistleblower Protection Act.

199. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

200. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTEEN
Iowa False Claims Law,
Iowa Code §§ 685.1 *et seq.*

201. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

202. This is a claim for treble damages and civil penalties under the Iowa False Claims Law, Iowa Code §§ 685.1 *et seq.*

203. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Iowa Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

204. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Iowa False Claims Act.

205. The Iowa Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

206. By reason of these payments, the Iowa Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT FOURTEEN
Louisiana Medical Assistance Programs Integrity Law,
La. Rev. Stat. §§ 46:437.1 *et seq.*

207. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

208. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437.1 *et seq.*

209. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

210. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Louisiana Medical Assistance Programs Integrity Law.

211. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

212. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT FIFTEEN
Maryland False Health Claims Act of 2010,
Md. Health Code Ann. §§ 2-601 *et seq.*

213. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

214. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act, Md. Health Code Ann. §§ 2-601 *et seq.*

215. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented

to the Maryland Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

216. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Maryland False Health Claims Act.

217. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

218. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT SIXTEEN
Massachusetts False Claims Law, Mass. Ann. Laws Ch. 12, § 5A-5O

219. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

220. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Ann. Laws Ch. 12, § 5A-5O.

221. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made, or used a false record or statement.

222. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Massachusetts False Claims Act.

223. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

224. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT SEVENTEEN
Michigan Medicaid False Claim Act, M.C.L.A. §§ 400.601 *et seq*.

225. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

226. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act, M.C.L.A. §§ 400.601 *et seq*.

227. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Michigan Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

228. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Michigan Medicaid False Claims Act.

229. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

230. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT EIGHTEEN
Minnesota Fraudulent State Claims Act, Minn. Stat. §§ 15C.01 *et seq.*

231. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

232. This is a claim for treble damages and civil penalties under the Minnesota Fraudulent State Claims Act, Minn. Stat. §§ 15C.01 *et seq.*

233. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Minnesota Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

234. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Minnesota False Claims Act.

235. The Minnesota Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

236. By reason of these payments, the Minnesota Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT NINETEEN
Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 *et seq.*

237. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

238. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 *et seq.*

239. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Montana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

240. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Montana False Claims Act.

241. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

242. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY
Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*

243. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

244. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*

245. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Nevada Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

246. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Nevada False Claims Act.

247. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

248. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-ONE
New Hampshire Medicaid Fraud and False Claims,
N.H. Rev. Stat. Ann. §§ 167:61 et seq.

249. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

250. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims, N.H. Rev. Stat. Ann. §§ 167:61 *et seq.*

251. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented

to the New Hampshire Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

252. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the New Hampshire Medicaid Fraud and False Claims Act.

253. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

254. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-TWO
New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq*.

255. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

256. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq*.

257. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

258. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the New Jersey False Claims Act.

259. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

260. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-THREE
New Mexico Medicaid False Claims Act,
N.M. Stat. Ann. 1978, §§ 27-14-1 *et seq*.

261. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

262. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. 1978, §§ 27-14-1 *et seq*.

263. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

264. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the New Mexico Medicaid False Claims Act.

265. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

266. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-FOUR
New York False Claims Act, N.Y. State Fin. Law §§ 187 *et seq.*

267. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

268. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law §§ 187 *et seq.*

269. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the New York Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

270. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the New York False Claims Act.

271. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

272. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-FIVE
North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq.*

273. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

274. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, 52 N.C. Gen. Stat. §§ 1-605 *et seq.*

275. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the North Carolina Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

276. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the North Carolina False Claims Act.

277. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

278. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-SIX
Oklahoma Medicaid False Claims Act, 63 Okl. St. §§ 5053 *et seq.*

279. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

280. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. St. §§ 5053 *et seq.*

281. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

282. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Oklahoma Medicaid False Claims Act.

283. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

284. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-SEVEN
Rhode Island State False Claims Act, R.I. Gen. Laws 1956, §§ 9-1.1-1 *et seq.*

285. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

286. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws 1956, §§ 9-1.1-1 *et seq.*

287. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Rhode Island Medicaid Program false or fraudulent claims for payment or approval and/or

knowingly accomplished these unlawful acts by using or causing to be used or made, a false record or statement.

288. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Rhode Island False Claims Act.

289. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

290. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-EIGHT
Tennessee Medicaid False Claims Act,
Tenn. Code Ann. §§ 71-5-181 *et seq.*

291. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

292. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*

293. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Tennessee Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

294. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Tennessee Medicaid False Claims Act and the Tennessee False Claims Act.

295. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

296. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-NINE
Texas Medicaid Fraud Prevention Act,
Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.*

297. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

298. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

299. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Texas Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

300. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Texas Medicaid Fraud Prevention Act.

301. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

302. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY
Virginia Fraud Against Taxpayers Act,
Va. Code Ann. §§ 8.01-216.1 *et seq*.

303. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

304. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq*.

305. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Virginia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

306. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Virginia Fraud Against Taxpayers Act.

307. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

308. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY-ONE
Washington Medicaid Fraud False Claims Act
Rev. Code Wash. §§ 74.66.005 *et seq*.

309. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

310. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Rev. Code Wash. §§ 74.66.005 *et seq*.

311. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Washington Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

312. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Washington Medicaid Fraud False Claims Act.

313. The Washington Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

314. By reason of these payments, the Washington Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY-TWO
Wisconsin False Claims For Medical Assistance Act,
Wis. Stat. §§ 20.931 *et seq.*

315. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

316. This is a claim for treble damages and civil penalties under the Wisconsin False Claims For Medical Assistance Act, Wis. Stat. §§ 20.931 *et seq.*

317. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

318. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Wisconsin False Claims Act.

319. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

320. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY-THREE
District of Columbia False Claims Act,
D.C. Code §§ 2-381.02 *et seq.*

321. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

322. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code §§ 2-381.02 *et seq*.

323. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by using or causing to be used or made, a false record or statement.

324. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the District of Columbia False Claims Act.

325. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

326. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY-FOUR
City of Chicago False Claims Act,
Chicago Mun. Code Chapter 1-22-010, *et seq*.

327. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

328. This is a claim for treble damages and civil penalties under the City of Chicago False Claims Act, Chicago Municipal Code Chapter 1-22-010, *et seq*.

329. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented

to the City of Chicago false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by using or causing to be used or made, a false record or statement.

330. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the City of Chicago False Claims Act.

331. The City of Chicago, unaware of the falsity or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

332. By reason of these payments, the City of Chicago has been damaged, and continues to be damaged, in a substantial amount.

VIII. PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Defendant, ordering that:

a. Defendant cease and desist from violating the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, the State and Municipal False Claims Acts, and the California Insurance Frauds Prevention Act;

b. Defendant pay not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendant's actions, plus the appropriate amount to the States and Municipalities under similar provisions of their False Claims Acts;

c. Defendant pay not less than $5,000 and not more than $10,000 for each and every fraudulent claim for compensation Defendant caused to be submitted in violation of the

California Insurance Frauds Prevention Act, plus an assessment not more than three times the amount of each claim;

d. The Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State and Municipal False Claims Acts and the California Insurance Frauds Prevention Act;

e. The Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State False Claims Acts and the California Insurance Frauds Prevention Act;

f. Defendant be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

g. Defendant disgorge all sums by which it has been enriched unjustly by its wrongful conduct; and

h. The United States, the States, Municipalities and the Relator recover such other relief as the Court deems just and proper.

CONFIDENTIAL
ATTORNEY WORK PRODUCT
[redacted]

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the Relator hereby demands a trial by jury.

Dated: February 2, 2015

s/Michael Burrage
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Attorneys for Relator Jamie Siegel

*Not admitted to practice in this district, but will file *pro hac vice* motions shortly.

CONFIDENTIAL
ATTORNEY WORK PRODUCT
[redacted]

CERTIFICATE OF SERVICE

I hereby certify that a copy of Plaintiff-Relator's Complaint was served upon the following persons, this 2nd day of February 2015, via first class mail, certified, return receipt requested.

s/Michael Burrage
Michael Burrage, Bar No. 1350

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The United States of America	
United States Attorney General Eric H. Holder United States Department of Justice 950 Pennsylvania Ave., N.W. Washington, DC 20530 United States Attorney for the Western District of Oklahoma Sanford C. Coats United States Attorney's Office 210 West Park Avenue, Suite 400 Oklahoma City, OK 73102 (405) 553-8700 (405) 553-8888 (fax)	United States Attorney General Eric H. Holder c/o Ms. Joyce R. Branda Deputy Director, Commercial Litigation Branch - Fraud Section U.S. Department of Justice Ben Franklin Station 950 Pennsylvania Avenue P.O. Box 261 Washington, DC 20530 (202) 307-0231 (202) 616-3085
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